

REMARKS



Claims 29-41, 43-93, 95, and 106-153 are currently pending in light of the amendments above. Claims 42, 94, and 96-105 have been canceled, without prejudice, and Applicants reserve the right to pursue the subject matter of these claims in this or related applications. Claims 35, 39-41, 44, 53, 66, 68, 70-73, 75-77, 79, 82-87, and 91-93 have been amended and new claims 106-153 have been added to more particularly point out and distinctly claim that which Applicants regard as the invention. The claims are completely supported in the specification as originally filed and no new matter has been introduced.

More specifically, support for claims 44, 75, and 128, with respect to transcription and translation regulatory elements to direct transcription and translation, can be found, for example, at page 17, line 1 to page 18, line 34 and Examples 1-3(b) (pages 54-62). Support for claim 106, with respect to 95% identity, can be found, for example, on pages 23 and 24. Support for claims 121 and 127, with respect to at least one conservative substitution, can be found, for example, on pages 21 and 22 (see, for example, page 21, lines 9-13; and page 22, line 7).

**The Claimed Subject Matter Is Adequately Described
And Enabled Under 35 U.S.C. § 112, First Paragraph**

Claims 96-105 have been rejected under 35 U.S.C. § 112, first paragraph (Office Action, item 3, pages 2-4). This rejection has been obviated by the cancellation of claims 96-105. Applicants respectfully request that the rejection of claims 96-105 be withdrawn.

Claims 29, 32-43, and 86-95 have been rejected under § 112, first paragraph, with respect to the availability of the recited deposited material (Office Action, item 4, pages 4-5). This rejection has been obviated by the Statement Concerning The Deposited Plasmid, submitted concurrently herewith. Therefore, Applicants respectfully request that the rejections to 29, 32-43, and 86-95 under § 112, first paragraph, be withdrawn.

Claims 42, 73, 84, 94 and 104 have also been rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement (Office Action, item 5, pages 5-7).

First, the Examiner contends that “the claims are drawn to a process of producing a protein but the claims are not limited to a process which employs a nucleic acid that encodes the protein produced by the claimed process” (Office Action, page 5).

Applicants note that claims 42, 94, and 104 have been canceled, without prejudice, and claims 73 and 84 have been amended to specify that the production of a polypeptide by those nucleic acid molecules encoding such polypeptides. In addition, Applicants note that new claims 119, 136, 145, and 153 have been drafted in a similar manner to address this issue.

Second, the Examiner contends that the specification does not enable polypeptides having an amino acid sequence that varies in any way from the amino acid sequence of SEQ ID NO:2. Specifically, the Examiner asserts:

Whereas the instant claims encompass a process of making a plurality of different proteins, the instant specification does not disclose how to make and use a protein comprising other than all or a specific portion of the amino acid sequence presented in SEQ ID NO:2 of the instant application.

Office Action, page 6. To the extent that this rejection applies to any of new claims, Applicants respectfully disagree.

The Examiner alleges that the polypeptide of SEQ ID NO:2 is the only species of polypeptide disclosed in the specification, and that this species cannot support a claim to a genus that encompasses polypeptides other than SEQ ID NO:2. The Examiner cites two cases to support this proposition: *In re Soll*, 97 F.2d 623, 25 C.C.P.A. 1309 (C.C.P.A. 1938) and *In re Wahlforss et al.*, 117 F.2d 270, 28 C.C.P.A. 867, 48 U.S.P.Q. 397 (C.C.P.A. 1941), as cited in *In re Clarke*, 356 F.2d 987 (C.C.P.A. 1966). Although the rejection is cast in terms of lack of enablement, these two cases appear to have been decided on the basis of a lack of adequate written description. However, in any event, the instant application clearly provides the enabling written description that the court found specifically lacking in these two cases.

In *Soll*, the description of the invention in the specification was clearly limited to one, single species. Other species in the later claimed genus were simply in no way described as being part of the invention. Specifically, the *Soll* court found the following:

...applicant has disclosed that he can use only hydrogen fluoride, since no implied or direct statements can be found in the application, as originally filed, that the other hydrogen halides will react similarly to give the same product.

Soll, 97 F.2d at 1311, emphasis added.

As a general rule, it is our opinion that in chemical cases, where an applicant does not refer to any substitutes for the particular material disclosed or give any indication that he regards his invention as generic in the application as filed, he is not entitled to broader claims than for the material originally disclosed.

Id., emphasis added

We think the rule is well settled that in a chemical case where an applicant discloses that one species of a class of chemical will accomplish a certain purpose without naming any others of the class to which it belongs or without so describing the species and its mode of operation as to call attention to the fact that other members of the class are its equivalents and will perform the same function, he is not entitled to broaden the scope of his disclosed invention by claiming the whole group...

Id. at 1312, emphasis added.

Appellant's applicant is barren of any suggestion that anything but hydrofluoric acid [i.e., the one species disclosed] will react upon rubber in the desired manner. There is no teaching in the application of the equivalency of the members of the group nor is there any member of the group named other than hydrofluoric acid.

Id. at 1313, emphasis added.

Wahlforss is even more distinguishable from the instant application. In *Wahlforss*, the court found not only that the specification fails to disclose the use of halogens other than the single halogen disclosed (chlorine), but that the specification "clearly teaches the nonuse, rather than the use of halogens." *Wahlforss*, 28 C.C.P.A. at 868, emphasis added.

In direct contrast to *Soll* and *Wahlforss*, the instant specification explicitly states, for example,

It will be recognized in the art that some amino acids of the galectin 11 polypeptide can be varied without significant effect of the structure or function of the protein. If such differences are contemplated, it should be remembered that there will be critical areas on the protein which determine activity. Thus, the invention further includes variations of the galectin 11 polypeptide which show substantial galectin 11 polypeptide functional activity or which include regions of galectin 11 protein such as the protein portions discussed below. Such mutants include deletions, insertions, inversions, repeats, and type substitutions.

Specification, page 20, line 33 to page 21, line 4. Specific guidance regarding the types of substitutions that can be made is then provided by the specification in detail on page 21, followed by a definition of conservative amino acid substitutions in Table 1, at page 22.

Thus, unlike in *Soll*, the instant specification a) explicitly describes that species of polypeptides other than SEQ ID NO:2 can be used in accordance with the invention, b) describes that the invention, therefore, encompasses this generic class of polypeptides, c) calls attention, quite explicitly, to the fact that other members of the class are its equivalents, and d) provides a teaching as to which members of this class would constitute such equivalents.

In further support of the rejection, the Examiner cites *In re Fisher* 427 F.2d 833, 57 C.C.P.A. 1099, 166 U.S.P.Q. 18 (C.C.P.A. 1970) for the proposition that the claimed genus is not commensurate with the disclosure. However, *Fisher*, like *Soll* and *Wahlforss*, is quite distinguishable from the instant case. In *Fisher*, the court took exception to the expressly recited range of activities of the claimed compounds, because the range was infinite -- it had no upper limit. *Fisher*, 57 C.C.P.A. at 1107-1108. The claim recited "at least 1 International Unit of ACTH per milligram," whereas the specification disclosed compounds with potencies of only 1.11 to 2.30 units. *Id.* at 1107. Thus, the applicant in *Fisher* was explicitly claiming the limitless genus of potencies extending beyond the upper limit of the disclosed range. *Id.* The instant claims contain no such limitless "open ended" recitations regarding the activities of the claimed compositions.

In any event, and more importantly, the instant specification provides detailed guidance to the skilled person to make and use the genus specified in the claims. Specifically regarding the guidance the specification provides, the Examiner contends:

Because the instant specification does not identify a structurally and functionally analogous protein for which this information is known and could be applied to a protein of the instant invention by analogy, an artisan can not look to the prior art for the needed guidance.

Office Action, pages 6-7. However, in direct contrast to the Examiner's assertion, the specification explicitly describes the "Galectin 11" polypeptide of SEQ ID NO:2 as a member of the "galectin" family of proteins, as the name itself clearly indicates (see Background of the Invention, pages 1-3). Moreover, the specification explicitly describes galectin family members rat galectin 5 and human galectin 1 and 3, and the activities of these human proteins, including the apoptosis-mediating activity of galectin 1 (page 2, lines 33-35 and Figure 2). Thus, this detailed description of the galectin family directly contradicts the Examiner's assertion that "the instant specification does not identify a structurally and functionally analogous protein for which this information is known and could be applied to a protein of the instant invention by analogy" (Office Action, pages 6-7). In addition, the homology of galectin 11 to rat galectin 5, as well as human galectin 8, showing regions of conservation, is explicitly depicted in detail in Figure 2. Therefore, the instant specification indeed provides the skilled artisan with guidance in altering the sequence of SEQ ID NO:2 to retain a desired function.

In fact, the skilled person could readily determine, for example, the regions of the polypeptide of SEQ ID NO:2 that are antigenic using methods very well known in the art. It is well established that a "patent applicant need not include in the specification that which is already known to and available to the public." *Paperless Accounting, Inc. v. Bay Area Rapid Transit System*, 804 F.2d 659, 664, 231 USPQ 649, ___ (Fed. Cir. 1986). Such an analysis would not require a homologous protein, but rather only the detailed description of the structure of the polypeptide provided by the amino acid sequence disclosed in the instant specification. Indeed, based on this amino acid sequence information, a protein profile of the polypeptide of SEQ ID NO:2, including a depiction of the antigenic regions, has been provided in Figure 3 of the instant application. The skilled person, provided the amino acid sequence of SEQ ID NO:2 alone, would readily be able to vary this amino acid sequence to make and use polypeptides that retain these antigenic regions.

In summary, the instant specification contains an explicit description of a class of polypeptides in accordance with the invention that encompasses SEQ ID NO:2. In addition, the specification provides detailed guidance to teach the alterations that can be made to SEQ ID NO:2 in order to make and use this class of polypeptides. Therefore, the instant specification provides an adequate written description to enable one skilled in the art to make and use the claimed polynucleotides encoding the specified class of polypeptides. Accordingly, Applicants respectfully request that the rejections under § 112, first paragraph be withdrawn.

**The Claimed Subject Matter Is Definite
Under 35 U.S.C. § 112, Second Paragraph**

Claims 42, 73, 84, 94, and 104 have been rejected under 35 U.S.C. § 112, second paragraph (Office Action, item 6, page 8). Specifically, the Examiner contends that the claims are vague and indefinite because there is no clear antecedent basis for “a polypeptide encoded by the nucleic acid of claim” since the claims from which they depend are not required to encode a polypeptide.

As noted above, claims 42, 94, and 104 have been canceled, without prejudice, and claims 73 and 84 have been amended to specify that the production of a polypeptide by those nucleic acid molecules encoding such polypeptides. In addition, Applicants note that new claims 119, 136, 145, and 153 have been drafted in a similar manner to address this issue. Thus, Applicants respectfully request that the rejection under § 112, second paragraph be withdrawn.

**The Claimed Subject Matter Is Novel Under 35 U.S.C. § 102
And Nonobvious Under 35 U.S.C. § 103**

Claims 29, 35, 36, 38, 40, 44 to 67, 69, 71, 75 to 78, 80, 82, 86 to 88, 90, 92, 96 to 98, 100 and 102 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Adams et al., Nature 377:3-17, 28 Sep. 1995, EST181872, GenBank Accession Number AA311108, (“Adams et al.”) (Office Action, item 7, pages 8-9).

Apparently, this rejection is premised upon the position that the sequence of GenBank Accession Number AA311108 was available on the publication date (September 28, 1995) of the Adams et al. reference. However, the Adams et al. reference

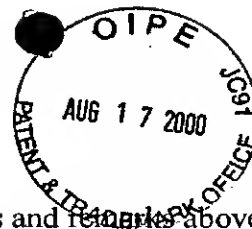
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does not contain the cited sequence. For the Examiner's convenience, Applicants submit herewith a Supplemental Information Disclosure Statement with a copy of the complete Adams et al. reference (pages 3-174) as reference C32. The complete Adams et al. reference does not contain the nucleotide sequence information of the cited GenBank Accession Number AA311108. Indeed, the report for GenBank Accession Number AA311108 is dated April 19, 1997, as noted by Applicants in submitting this report with the Information Disclosure Statement filed on December 7, 1999 (reference C6). Thus, in contrast to the Examiner's assertion, the cited nucleotide sequence of GenBank Accession Number AA311108 was not publicly available until April 19, 1997, which is after the January 21, 1997 priority date, and less than one year before the January 21, 1998 priority date, for the instant application.

Therefore, Applicants respectfully submit that the rejection under § 102(b) is based on an incorrect interpretation of the publication date of the cited reference. Accordingly, Applicants respectfully request that the rejection under § 102(b) be withdrawn.

Claims 43, 85, 95 and 105 have been rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Adams et al. (Office Action, item 8, page 9). This rejection is also premised on the assumption that the cited nucleotide sequence of GenBank Accession Number AA311108 was available on the September 28, 1995 publication date of the Adams et al. reference. However, as detailed above, the publication date provided in the report for GenBank Accession Number AA311108 is April 19, 1997. Thus, for the same reasons detailed above for rejection of claims 29, 35, 36, 38, 40, 44 to 67, 69, 71, 75 to 78, 80, 82, 86 to 88, 90, 92, 96 to 98, 100 and 102, Applicants respectfully request that the rejection of claims 43, 85, 95 and 105 under § 102(b) or § 103(a) be withdrawn.

CONCLUSION




Applicants respectfully request that the amendments and ~~renewals~~ above be entered and made of record in the file history of the instant application. Applicants believe that the application is now in condition for allowance and a notice to that effect is earnestly solicited.

If there are any additional fees due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

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